



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,639	05/16/2001	Nissim Darvish	20066.73	3851
54042 7590 02/14/2008 WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP 250 PARK AVENUE 10TH FLOOR NEW YORK, NY 10177			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT, 3762	PAPER NUMBER
			NOTIFICATION DATE 02/14/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

Office Action Summary	Application No.	Applicant(s)	
	09/720,639	DARVISH ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,10-15,55,56,59-64,151-177 and 205-214 is/are pending in the application.
- 4a) Of the above claim(s) 152-154,156-160,165 and 169-171 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,7,55 and 56 is/are allowed.
- 6) ☒ Claim(s) 10-15,59-64,151,155,161-164,166-168,172-177,205-214 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/28/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 61, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12/61 are vague since they conflict with claims 10/59 since claims 10/59 has the train being at least 8 ms and claims 12/61 have the train being "at least 5 ms".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 205, 206, and 209-214 are rejected under 35 U.S.C. 102(b) as being anticipated by Whigham et al (4821724). Whigham shows in figure 4 a multiphasic single pulse/stimulus that has an overall duration greater than 8 ms from a portion of the signal that initiates the action potential. It is noted that the pulse has a stimulus phase of 0.5 msec and a postcharge phase of 8 msec (e.g. col. 6 and 12). In addition, the claim states "either cathodic or anodic" which Whigham meets since his pulse contains both anodic and cathodic phases. It is noted that the claim does not state that the pulse is "only" or "entirely" cathodic or anodic (and it appears there is NO support in the specification for this limitation also). Finally, Whigham states that his pulse is approximately 7.5 volts which is an amplitude of approximately 15 times as great a threshold for pacing (see the strength duration curves, such as in US patent 5447525).

Claims 10-13, 15, 59-62, 64, 151, 155, 161-164, 166-168, 172, 173, 175, 176, and 177 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehra (5683429). Mehra states his pulses are 1.0 ms in width and includes approximately 10 pulses, and therefore is a train of pulses of at least 10 msec and meets the claimed limitation of "greater than 8 msec". Mehra also operates at a frequency of 200 Hz (e.g. columns 11 and 12), providing a 50 msec pulse train that has an overall duration of the signal such that the signal terminates during the refractory period. Mehra states that his pulse is approximately 15 volts which is an amplitude of approximately 30 times as great a threshold for pacing (see the strength duration curves, such as in US patent 5447525). Finally, since the pulses are meant to increase pumping output to normal and since the pacing pulses are of a similar duration as the applicants, the pulses of Mehra WILL modify a characteristic of pulsatile flow, increase contractility by at least 10% relative to a 2ms duration pulse, and engenders a redistribution of cardiac muscle mass.

Art Unit: 3762

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 161-164, 166, 167, 172-174, and 176 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mehra. Mehra senses P waves and APBs (electrophysiological signals, MAPs) and operates in the AAI mode to determine when the heart is not beating properly to deliver the lower energy pacing signal and extended pacing train and therefore senses a demand for enhancement of hemodynamic performance and modifies the signal by delivering the signal or not delivering the pacing and extended pacing signal. In addition, Mehra uses a CS lead for the left atrial chamber and is the other chambers lead/electrodes.

In the alternative, Mehra discloses the claimed invention except for sensing a demand or MAP/electrophysiological signal representative of the activity of the heart for enhancement to

Art Unit: 3762

convey the pacing signal (claims 164, 166, 172-174) or detecting a possible arrhythmia to modify the pacing signal and the use of a lead in another chamber (a left atrial lead for the CS lead). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the pacing system and method as taught by Mehra the use of sensing a demand or MAP/electrophysiological signal representative of the activity of the heart for enhancement to convey the pacing signal (claims 164, 166, 172-174) or detecting a possible arrhythmia to modify the pacing signal and the use of another lead in another chamber since it was known in the art that pacing systems and methods use: sensing a demand or MAP/electrophysiological signal representative of the activity of the heart for enhancement to convey the pacing signal to provide the predictable results of allowing the pacemaker to easily and conventionally determine when the heart is not and is functioning properly to deliver or not deliver the pacing signal when needed; and detecting a possible arrhythmia to modify the pacing signal to provide the predictable result of allowing the system to adjust the signal to the demands and needs of the patient based on the patients particular condition or history; and using another lead in another chamber to provide the predictable results of a lead located directly in the chamber so that chamber is the only area stimulated, other areas of the heart are not stimulated, and to use a lower pacing energy to directly stimulate that particular area to reduce battery drain.

Claims 14, 63, 207, and 208 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra. Mehra discloses the claimed invention except for using biphasic pulses and a train with 2 pulses having a duration of at least 5 ms per pulse. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulses as taught by Mehra, with biphasic pulses since it was known in the art that cardiac systems use biphasic

Art Unit: 3762

pulses to provide the predictable results of balancing the charge delivered to the heart and preventing degradation of the electrodes. In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the train of pulses as taught by Mehra with the two pulses having a duration of at least 5 msec per pulse, because Applicant has not disclosed that the two pulses having a duration of at least 5 msec per pulse provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the train of 10 pulses of 1msec per pulse as taught by Mehra, because it effectively provides a way to stimulate the heart with an extended pacing signal to prevent fibrillation and enhance heart function.

Therefore, it would have been an obvious matter of design choice to modify Mehra to obtain the invention as specified in the claim(s).

Allowable Subject Matter

Claims 6, 7, 55, and 56 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

12/30/07

GRE
12/30/07